# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:

Roberts, *et al.*

(Cont. of Appl. No.: 09/631,116)

Filed: herewith

Appl. No.: to be assigned

For: **Novel Compounds with Analgesic Effect**

Art Unit: to be assigned
(1624 in parent case)

Examiner: to be assigned
(E. Bernhardt in parent case)

Atty. Dkt.: 7567/80871

## Information Disclosure Statement

Commissioner of Patents
U.S. Patent and Trademark Office
2011 South Clark Place
Customer Window, **MS Patent Application**
Crystal Plaza Two, Lobby, Room 1B03
Arlington, VA 22202

Sir:

Submitted herewith is a listing of documents known to Applicants and/or their attorney in compliance with the requirements of 37 C.F.R. § 1.56. Copies of the listed documents are also enclosed.

Applicants also wish to make the Examiner aware of co-pending applications 10/240,037, filed on September 27, 2002; 10/149,911, filed on October 21, 2002; and 10/149,981, filed on October 21, 2002.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned attorney submits the following concise explanation of the relevance of the non-English language documents cited on the accompanying form:

Reference B15, French patent document FR 2 696 744, describes 1-(2-2,-dimethyl-propyl)-2-pyrrolidone derivatives useful, *inter alia*, as serotonin 5HT-2 antagonists. An English language abstract corresponding to this document is included herewith and is cited on the accompanying list of references as document C18.

Reference B16, German patent document DE 24 31 178, describes substituted cinnamoyl-piperazine-pyridyl compounds that have analgesic properties. An English language abstract corresponding to this document is included herewith and is cited on the accompanying list of references as document C19. Also, a corresponding U.S. patent (3,940,386) is cited as document A1.

Reference B17, German patent document DE 29 00 810, describes antidepressant N-benzhydryl-N′-hydroxyl-benzyl-piperazine derivatives. An English language abstract corresponding to this document is included herewith and is cited on the accompanying list of references as document C20.

Reference B18, Japanese patent document JP 7-138230, describes piperazine derivatives that act as allergy inhibitors. English abstracts corresponding to this document are cited on the accompanying list of references as documents C21, C22 and C23.

Reference C16, abstract of Hungarian patent reference HU 217619 describes piperazinecarboxamides containing phenoxyalkyl or thiophenoxyalkyl side chains. The reference also describes pharmaceutical compositions containing these compounds as active ingredients and processes by which they may be produced. A corresponding English language PCT application is included herewith and is cited on the accompanying list of references as document B1.

Reference C17, abstract of Hungarian patent reference HU 215847 describes a process for producing L-(-)-phenyl-piperazineacetamide derivatives. The reference also describes pharmaceutical compositions containing these derivatives that can be used for preventing or

limiting reperfusion damage. A corresponding English language PCT application is included herewith and is cited on the accompanying list of references as document B2.

Applicants do not waive any rights to appropriate action to establish patentability over any of the listed documents should they be applied as references against the claims of the present application. This statement should not be construed as a representation that more material information does not exist or that an exhaustive search of the relevant art has been made.

Consideration of the cited documents and making the same of record in the prosecution of the above-captioned application are respectfully requested.

Applicants do not believe any fees are due for the submission of this Information Disclosure Statement other than those which have been provided. However, the Commissioner is hereby authorized to charge any fee deficiency to our Deposit Account No. 06-1135 under Order No. 7567/80871.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

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| LIST OF REFERENCES CITED BY APPLICANT<br>*(Use several sheets if necessary)* | Atty. Docket No.: 7567/80871 | Appl. No.: to be assigned |
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| | Applicant(s) Roberts, *et al.* | |
| | Filing Date: herewith | Group: to be assigned |

U.S. PATENT DOCUMENTS

| Examiner Initial | | Document Number | Date | Name | Class | Subclass | Filing Date If Appropriate |
|---|---|---|---|---|---|---|---|
| | A 1 | 3,940,386 | Feb. 24, 1976 | Szabo, *et al.* | 260 | 240 | Jun. 21, 1974 |
| | A 2 | 5,574,159 | Nov. 12, 1996 | Chang, *et al.* | 544 | 396 | Apr. 28, 1995 |
| | A 3 | 5,681,830 | Oct. 28, 1997 | Chang, *et al.* | 514 | 85 | Aug. 3, 1994 |
| | A 4 | 5,807,858 | Sep. 15, 1998 | Chang, *et al.* | 514 | 255 | Jun. 5, 1996 |
| | A 5 | 6,130,222 | Oct. 10, 2000 | Roberts, *et al.* | 514 | 255.04 | Apr. 24, 1997 |
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| | B 1 | WO 86/04584 | 14 August 1986 | WIPO | C07D | 295/14 | | |
| | B 2 | WO 91/07967 | 13 June 1991 | WIPO | A61K | 31/495 | | |
| | B 3 | WO 93/15062 | 5 August 1993 | WIPO | C07D | 241/04 | | |
| | B 4 | WO 95/04051 | 9 February 1995 | WIPO | C07D | 295/155 | | |
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| | B 12 | EP 0 133 323 | 20 February 1985 | EPO | C07D | 295/04 | | |
| | B 13 | GB 2 210 366 | 7 June 1989 | Great Britain | C07D | 295/04 | | |
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| Examiner Initial | | OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) |
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| | C 1 | Bilsky, *et al.*, "Characterization of Enantiomers of (±)BW373U86 and Related Compounds: Highly Selective Non-Peptidic Delta Opioid Agonists," *Reg. Peptides 54*:25-26 (1994). |
| | C 2 | Bilsky, *et al.*, "SNC 80, A Selective, Nonpeptidic and Systemically Active Opioid *Delta* Agonist," *J. Pharmacol. Exper. Therap. 273*:359-366 (1995). |
| | C 3 | Burkey, *et al.*, "The Efficacy of Delta-Opioid Receptor-Selective Drugs," Medline Abstract for *Life Sci. 62*:1531-1536 (1998). |
| | C 4 | Calderon, *et al.*, "Probes for Narcotic Receptor Mediated Phenomena. 19. Synthesis of (+)-4-[(α*R*)-α-((2*S*,5*R*)-4-Allyl-2,5-Dimethyl-1-Piperazinyl)-3-Methoxybenzyl]-*N*,*N*-Diethylbenzamide (SNC 80): A Highly Selective, Nonpeptide δ Opioid Receptor Agonist," *J. Med. Chem. 37*:2125-2128 (1994). |
| | C 5 | Calderon, *et al.*, "Probes for Narcotic Receptor Mediated Phenomena. 23. Synthesis, Opioid Receptor Binding, and Bioassay of the Highly Selective δ Agonist (+)-4-[(α*R*)-α-((2*S*,5*R*)-4-Allyl-2,5-Dimethyl-1-Piperazinyl)-3-Methoxybenzyl]-*N*,*N*-Diethylbenzamide (SNC 80) and Related Novel Nonpeptide δ Opioid Receptor Ligands," *J. Med. Chem. 40*:695-704 (1997). |
| | C 6 | Chang, *et al.*, "A Novel, Potent and Selective Nonpeptidic *Delta* Opioid Receptor Agonist BW373U86," *J. Pharmacol. Exper. Therap. 267*:852-857 (1993). |
| | C 7 | Greene, "Protective Groups in Organic Synthesis," pp. 267-268 and 331 (1981). |
| | C 8 | Katrizky, *et al.*, "Benzotriazole-Mediated Arylalkylation and Heteroarylalkylation," *Chem. Soc. Rev. 23*:363-442 (1994). |
| | C 9 | Kingsbury, *et al.*, "Synthesis of Structural Analogs of Leukotriene $B_4$ and Their Receptor Binding Activity," *J. Med. Chem. 36*:3308-3320 (1993). |
| | C 10 | Lopez, *et al.*, "Exploring the Structure-Activity Relationships of [1-(4-*tert*-Butyl-3′-Hydroxy)Benzhydryl-4-Benzylpiperazine] (SL-3111), a High-Affinity and Selective δ-Opioid Receptor Nonpeptide Agonist Ligand," *J. Med. Chem. 42*:5359-5368 (1999). |
| | C 11 | Nagase, *et al.*, "The Pharmacological Profile of Delta Opioid Receptor Ligands, (+) and (-) TAN-67 on Pain Modulation," Medline Abstract for *Life Sci. 68*:2227-2231 (2001). |
| | C 12 | Plobeck, *et al.*, "New Diarylmethylpiperazines as Potent and Selective Nonpeptidic δ Opioid Receptor Agonists with Increased *In Vitro* Metabolic Stability," *J. Med. Chem. 43*:3878-3894 (2000). |
| | C 13 | Suggs, *et al.*, "Facile Synthesis of 8-Substituted Quinolines," *J. Org. Chem. 45*:1514-1515 (1980). |
| | C 14 | Takemori, *et al.*, "Selective Natrexone-Derived Opioid Receptor Antagonists," *Annu. Rev. Pharmacol. Toxicol. 32*:239-269 (1992). |
| | C 15 | Zhang, *et al.*, "Probes for Narcotic Receptor Mediated Phenomena. 26. Synthesis and Biological Evaluation of Diarylmethylpiperazines and Diarylmethylpiperidines as Novel, Nonpeptidic δ Opioid Receptor Ligands, *J. Med. Chem. 42*:5455-5463 (1999). |
| | C 16 | Abstract for HU 217619; a corresponding English language PCT application is cited above as reference B1. |
| | C 17 | Abstract for HU 215487; a corresponding English language PCT application is cited above as reference B2. |
| | C 18 | English language abstract for FR 2 696 744, Reference B15 above. |

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|---|---|---|
| | C19 | English language abstract for DE 24 31 178, Reference B16 above. |
| | C 20 | English language abstract for DE 29 00 810, Reference B17 above. |
| | C 21 | English language abstract for JP 7-138230, Reference B18 above. |
| | C 22 | English language abstract for JP 7-138230, Reference B18 above. |
| | C 23 | Abstract No. 8843b for JP 7-138230, Reference B18 above, *Chemical Abstracts 124*:938 (1996). |
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